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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/624,530 | 07/24/2000 | Richard Sackler | 200.93185C2C | 5659 |

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| EXAMINER | |
|---|---|
| CHONG, YONG SOO | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/624,530 | SACKLER ET AL. | |
| | Examiner | Art Unit | |
| | Yong S. Chong | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *6,7,13-16 and 24-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-7, 13-16, 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Application*

This Office Action is in response to applicant's arguments filed on 6/28/2007. Claim(s) 1-5, 9-12, 17-23 have been cancelled. Claim(s) 6-7, 13-16, 24-30 are pending. Claim(s) 6 and 24 have been amended. Claim(s) 6-7, 13-16, 24-30 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified below as a result of the claim amendments.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-8, 13-16, 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldie et al. (USPN 4844909).

Goldie et al. teaches a solid release oral dosage form, the dosage form comprising a therapeutically effective amount of hydromorphone or salt thereof in a matrix wherein the dissolution rate in vitro of the dosage form, when measured by the USP Paddle Method of U.S. Pharmacopeia XXII (1990) at 100 rpm at 900 mL aqueous buffer at pH 1.6 and 7.2 and at 37 °C overlaps with those as instantly claimed

(Abstract). Peak plasma level is achieved between 2 and 4 hours (Abstract). The amount of hydromorphone released at a pH of 1.6 is less than 10% than that released at any pH up to 7.2 (col. 1, lines 29-35). Therapeutic levels of hydromorphone are maintained in vivo for *at least* 12 hours (col. 2, lines 3-10). Compositions wherein peak plasma levels are achieved between 4 and 8 hours are also taught to provide at least 12 hours of therapeutic effect (col. 2, lines 11-23). Gums, cellulose ethers, acrylic resins, C8-C50 long chain hydrocarbons, fatty acids, fatty alcohols, mineral oils, vegetable oils, waxes and polyalkylene glycols are disclosed as matrix materials (col. 2, line 47-col. 3, line 6). Dosage forms comprising between 2 and 40 mg of hydromorphone are taught (col. 2, lines 41-46). Blood plasma levels are exemplified as 1.0 ng/mL and 2.1 ng/mL at 12 hours and 1.1 ng/mL and 1.4 ng/mL at 24 hours (Tables 5 and 6). Goldie et al. also teach a dosage form comprising film-coated spheroids. The spheroids may contain water insoluble polymers, such as acrylic polymer and ethyl cellulose. The spheroids are film coated with a material that permits release of the active agent in a controlled rate. The film coat includes a water insoluble polymer, such as ethyl cellulose (col. 3, line 66 to col. 4, line 59).

Goldie et al. does not specifically disclose a dosage form wherein the peak plasma level is obtained between 4.42 and 8 hours after administration of the dosage form.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a dosage form wherein the peak plasma level is between 4.42 and 8 hours after administration of the dosage form because it is well known in the

pharmaceutical art to have produced a formulation that gives a peak plasma level of the drug between 4 to 8 hours after adminsitration. One would have been motivated to prepare a dosage form, which achieved maximum plasma levels between 4.42 to 8 hours because of an expectation of similar success in preparing a dosage form, which achieved therapeutic effects for at least 12 hours.

Furthermore, even if between 2 and 4 hours is not considered inclusive of 4 hours, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a dosage form with a the peak plasma level obtained between 4 and 8 hours after administration of the dosage form because Goldie et al. teaches that dosage forms achieving a peak plasma level between 2 and 4 hours are, surprisingly, interchangeable with dosage forms that achieve peak plasma levels between about 4 and 8 hours after administration. Both dosage forms are taught to achieve the desired effect. Namely, both are taught to achieve a therapeutic effect for at least 12 hours. Accordingly, one would have been motivated to administer a dosage form that achieves a peak plasma level between 4 and 8 hours after administration because of an expectation of administering a dosage form suitable for achieving a therapeutic effect for at least 12 hours.

It is noted that the exemplified clinical studies teach plasma levels at 24 hours wherein the amount present is a therapeutically effective amount because (1) the dosage form is taught to be therapeutically effective for at least 12 hours and the plasma levels at 24 hours are not significantly different than the plasma levels at 12

hours; and (2) the plasma levels are within the scope of the plasma levels as instantly claimed in claim 20.

### *Response to Arguments*

Applicant's arguments with respect to the hydrophobic polymer coating have been addressed in the modified obviousness rejection above.

Applicant argues that Goldie fails to recognize the art recognized problem that dissolution release profile change on ageing.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER